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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/851,138	05/09/2001	Geert Maertens	2752-43	4881
23117	7590	07/28/2004	EXAMINER	
NIXON & VANDERHYE, PC 1100 N GLEBE ROAD 8TH FLOOR ARLINGTON, VA 22201-4714			LI, BAO Q	
			ART UNIT	PAPER NUMBER
			1648	

DATE MAILED: 07/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	09/851,138		MAERTENS ET AL.	
	Examiner		Art Unit	
	Bao Qun Li		1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 63-70 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 63-70 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 08/836,075.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>June 02, 2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 63-70 are pending.

Petition Under Rule 181

This action is responsive to the March 7, 2001 Response and the March 7, 2001 Alternate Rule 181 Petition (copy resubmitted on March 13, 2003). As indicated in the Interview Summary Record of September 13, 2001, the Office Action of June 1, 2001 has been vacated in order to permit the entry of a new restriction requirement set forth below. The response and petition are being treated as requests for reconsideration of the previous requirement. Accordingly, Applicant is given a new opportunity to elect in conformance with the new restriction requirement.

Restriction/Election Requirement

In view of applicants' petition, upon reconsidering all pending claims 63-70, the restriction/election on current pending claims 63-70 are withdrawn. Claims 63-70 are rejoined and considered before the examiner. A new Non-Final Office Action for the pending claims 63-70 follows:

Priority

1. MPEP 1893.03(b) [R-1] Recites: The Filing Date of a U.S. National Stage Application An international application designating the U.S. has two stages (international and national) with the filing date being the same in both stages. Often the date of entry into the national stage is confused with the filing date. It should be borne in mind that the filing date of the international stage application is also the filing date for the national stage application. Specifically, 35 U.S.C. 363 provides that An international application designating the United States shall have the effect, from its international filing date under Article 11 of the treaty, of a national application for patent regularly filed in the Patent and Trademark Office except as otherwise provided in section 102(e) of this title.
2. Similarly, PCT Article 11(3) provides that ...an international filing date shall have the effect of a regular national application in each designated State as of the international filing date, which date shall be considered to be the actual filing date in each designated State.

3. In the instant case, the priority of the current applicant is acknowledged to the international filing date of the internally PCT application WO 96/13590A3, which examiner has found it in a certified copy in the parent case 08//836,075. Therefore, the filing date of the current application is considered as the same international filing date of October 23, 1995.

4. MPEP 1895.01 recite: An application filed under 35 U.S.C. 111(a) may make a claim for foreign priority under 35 U.S.C. 119 (a)-(d) and 365(a) to an international application which designates at least one country other than the United States (the U.S. may also be designated). In this situation, applicant must file a certified copy of the international application in the application filed under 35 U.S.C. 111(a) and the applicant must satisfy all other requirements of 35 U.S.C. 119(a)-(d)

5. In the instant case, acknowledgment is made of applicant's claim for foreign priority based on an application filed in EP 94870166.9 on October 21, 1994. It is noted, however, that applicant has not filed a certified copy of the EP 94870166.9 application as required by 35 U.S.C. 119(b).

Claim Rejections - 35 USC § 101

1. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Art Unit: 1648

Claims 63-65 and 69 are rejected under 35 U.S.C. 101 as claimed invention is directed to non-statutory subject matter. There is no recitation of isolation or synthesis in front of the claimed subject matter. Therefore, the claimed product read on naturally occurring materials, which are considered to be non-statutory and non-patentable subject matter within the scope of 35 U.S.C. 101. See Official Gazett, 1077 O.G. April 21, 1987. It is recommended that the claim incorporate the claim language, “ isolated or synthesized” to overcome this rejection.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 64, 66, 67, 68, and 70 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 64 is vague and indefinite in that the metes and bounds of recited “a polynucleic acid” are not defined. The claim only recites that the polynucleic acid encoding an HCV polyprotein comprising its amino acid sequence comprising G217 and C252. However, the claim fails to define which HCV polyprotein is intended. Therefore, the structural characteristic of claim polynucleic acid sequence is unclear since there is no indication from where the counting of the amino acid residue of claimed HCV polyprotein starts. This affects the dependent claim 66, 67, 68 and 70.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Art Unit: 1648

6. Claims 63, 64 and 65 are rejected under 35 U.S.C. 102(b) as being anticipated by van Doorn et al. (J. Hepatology July 1994, Vol. 21(1), pp. 122-129).

7. van Doorn et al. discloses an isolated HCV polypeptide and its encoded polypeptide consisting of 447 nucleic acids, which has 100% homology to the claims polynucleotide sequence of SEQ ID NO: 51. The polynucleotide disclosed by van Doorn et al. encodes a polypeptide comprising a fragment having 100% sequence identical to the claims polypeptide comprising a fragment having an amino acid sequence selected from the group consisting of SEQ ID NO: 138, 155, 174, and 190 (Fig. 2 on pages 126-127, especially see the sequence search report provided by PTO). Therefore, the claimed invention is anticipated by the cited reference.

8. Applicants are reminded on the record that the above rejection is based on that the filing date of current application considered as October 23, 1995 because the a certified copy of the priority document: EP 94870166.9 has not been provided in the current application as well as in the parent application SN. 08/836,075. If the certified copy of the foreign application EP 94870166.9 is provided and considered as the same disclosure as the international application SN. WO/96/13590A3, the cited reference will be 102 (a) reference.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 571-272-0904. The examiner can normally be reached on 7:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

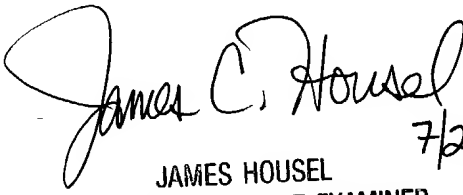
Art Unit: 1648

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Bao Qun Li

Art Unit 1648

July 22, 2004


JAMES HOUSEL
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
7/26/04